510(k) SUMMARY

DEC 17 2002

Name of 510(k) sponsor: Address:	ATI Medical, Inc. 10954-A Via Frontera San Diego, CA 92129 Telephone: 858 487-7243 Fax: 858 487-7763
Contact information:	Michael Wienholt, RAC Regulatory Affairs Manager ATI Medical, Inc. Telephone: 858 487-7243, ext. 28 Fax: 858 487-7763 E-mail: mwienholt@atimedical.com
Date summary prepared:	March 2, 2002
Proprietary name of device:	IsoRod Pd-103 Implant
Generic/classification name:	Brachytherapy Source
Product code (classification):	Source, Radionuclide, Brachytherapy 21 C.F.R. § 892.5730

Legally Marketed Predicate Devices:

GENETRA (K013660)
TheraSeed Palladium (K010283)
InterSeed (K973328)

Device Description and Technological Characteristics:

The IsoRod implant is a permanently implanted, radioactive device, designed for the treatment of deep- seated tumors. IsoRod implants are comprised of base metallic rods that are coated with radioactive palladium. The radioactive palladium is then encapsulated with a metallic coating.

The base rod is composed of a palladium/cobalt alloy. The rod is 1 millimeter in diameter and 10 millimeters in length. The thin layer (0.2 micron) that comprises the radioactive layer is a combination of radioactive and non-radioactive palladium (Pd-103 and Pd-102 respectively). The encapsulation layer of 6-8 microns is pure palladium, a metal that is utilized in permanent implants based on its favorable biocompatibility characteristics.

The activity of each IsoRod implant is between 0.5 mCi and 3.0 mCi. The source is exceptionally isotropic based on the fact that the radioactive material is evenly deposited on the source and is shielded in every direction only by the thin layer of non-radioactive palladium.

Intended Use

The ATI Medical, Inc. IsoRod Pd-103 Radionuclide Brachytherapy Source is intended for permanent interstitial implantation for the treatment of selected localized tumors with low to moderate radiosensitivity. They are used either as primary treatment for tumors such as those of the head, neck, lung, intra-abdominal, pancreas, prostate, and unresectable tumors, or for residual disease after excision of primary or secondary tumors. IsoRod Pd-103 implants may be used concurrently with or following treatment with other interventions, such as external beam therapy, hyperthermia, or chemotherapy.

Testing

The dosimetry of the IsoRod implants was determined by Monte Carlo analysis at UCLA using the MCNP P version 4C Monte Carlo code developed at Los Alamos National Laboratory. Physical dose measurements in a phantom will be completed prior to marketing.

The results of the biocompatibility tests are summarized at Appendix 7 and indicate that the IsoRod Pd-103 implant is biocompatible under the conditions of intended use.

Conclusions

The ATI Medical, Inc. IsoRod Pd-103 Implant has the same indications for use and similar technological characteristics (e.g., isotope; apparent activity) as the predicate devices. Biocompatibility testing has established that IsoRod implants are biocompatible under the conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2002

Mr. Michael Wienholt, RAC
Director, Regulatory Affairs & QA
ATI Medical, Inc.
10954 Via Frontera, Suite A
SAN DIEGO CA 92127

Re: K020683
Trade/Device Name: IsoRod Pd-103 Implant
Brachytherapy Source
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: September 17, 2002
Received: September 18, 2002

Dear Mr. Wienholt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: **ATI Medical, Inc.**

510(k) Number: **K020683**

Device Name: **IsoRod Pd-103 Radionuclide Brachytherapy Source** (Implant)

Indications for Use:

The ATI Medical, Inc. IsoRod Pd-103 Radionuclide Brachytherapy Source is intended for permanent interstitial implantation for the treatment of selected localized tumors with low to moderate radiosensitivity. They are used either as primary treatment for tumors such as those of the head, neck, lung, intra-abdominal, pancreas, prostate, and unresectable tumors, or for residual disease after excision of primary or secondary tumors. IsoRod Pd-103 implants may be used concurrently with or following treatment with other interventions, such as external beam therapy or chemotherapy.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the Counter Use _____

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020683